UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of report (Date of earliest event reported) **March 10, 2022**

Oncternal Therapeutics, Inc.
(Exact Name of Registrant as Specified in Charter)

Delaware	**000-50549**	**62-1715807**
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(IRS Employer Identification No.)

12230 El Camino Real
Suite 300
San Diego, CA 92130
(858) 434-1113
(Address and zip code; telephone number, including area code, of registrant's principal executive offices)

N/A
(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (*see* General Instruction A.2. below):

☐ Written communication pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Common Stock, par value $0.001 per share	ONCT	The Nasdaq Stock Market, LLC

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 2.02. Results of Operations and Financial Condition.

On March 10, 2022, Oncternal Therapeutics, Inc., issued a press release announcing its financial results for the fourth quarter and year ended December 31, 2021. A copy of this press release is attached hereto as Exhibit 99.1.

In accordance with General Instruction B.2 of Form 8-K, the information in this Current Report on Form 8-K, including Exhibit 99.1, shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liability of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, whether made before or after the date hereof, except as expressly set forth by specific reference in such filing to this Current Report on Form 8-K.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press Release, dated March 10, 2022
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Oncternal Therapeutics, Inc.

Date: March 10, 2022

By: /s/ Richard G. Vincent

Name: Richard G. Vincent

Title: Chief Financial Officer

Exhibit 99.1

Oncternal Therapeutics Provides Business Update and Announces Fourth Quarter and Full Year 2021 Financial Results

- *Reached consensus with the FDA on the design and major details of the global Phase 3 Study ZILO-301 to treat patients with relapsed or refractory MCL with zilovertamab plus ibrutinib, which is on track to be initiated in the second quarter of 2022*
- *Interim Phase 1/2 results for zilovertamab plus ibrutinib in MCL and CLL presented at ASH in December 2021 compare favorably to historical single agent ibrutinib data and support moving into Phase 3 Study ZILO-301*
- *Progressed the development of ONCT-808, the lead candidate for our autologous CAR-T program targeting ROR1-expressing malignancies, with IND submission on track for mid-2022*
- *Selected and advanced ONCT-534, the lead candidate in our novel dual-action androgen receptor inhibitor (DAARI) program into IND enabling studies*
- *Two complete responses in patients with metastatic relapsed/refractory Ewing sarcoma treated with ONCT-216 in ongoing Phase 1/2 clinical trial remain durable; dose intensive cohort data expected in fourth quarter of 2022*
- *Management to host webcast today at 5:00 pm ET*

SAN DIEGO, March 10, 2022 -- Oncternal Therapeutics, Inc. (Nasdaq: ONCT), a clinical-stage biopharmaceutical company focused on the development of novel oncology therapies, today provided a business update and reported fourth quarter and full year 2021 financial results.

"This past year was a decisive one for Oncternal, as we reached consensus with the FDA on our Phase 3 clinical trial ZILO-301 of zilovertamab in patients with MCL, advanced our ROR1-targeting CAR-T cell therapy candidate ONCT-808 towards IND submission, and initiated IND-enabling studies for ONCT-534, our DAARI product candidate that may address key resistance mechanisms in metastatic prostate cancer," said James Breitmeyer, M.D., Ph.D., Oncternal's President and CEO. "We are focusing our resources on hematological malignancies and prostate cancer, areas of high unmet patient need where we believe our potentially first-in-class or best-in-class product candidates can make the greatest difference. We believe our strong balance sheet will enable us to advance these programs into mid-2023, as we navigate a historically challenging macro environment."

Recent Highlights

- In January 2022, we announced that we reached consensus with the FDA on the design and major details of the Phase 3 Study ZILO-301 to treat patients with relapsed or refractory mantle cell lymphoma (MCL) with zilovertamab, an investigational anti-ROR1 monoclonal antibody, in combination with ibrutinib. The agency also provided positive feedback on the proposed key clinical and regulatory requirements of our development program for zilovertamab in patients with MCL.
- In December 2021, we announced an interim clinical data update from the ongoing Phase 1/2 clinical trial of zilovertamab in combination with ibrutinib for patients with MCL and chronic lymphocytic leukemia (CLL) [NCT03088878] at the American Society of Hematology (ASH) 2021 Virtual Annual Meeting.
    - Objective response rate (ORR) of 81% (21 of 26 evaluable patients) observed for patients with MCL treated with zilovertamab plus ibrutinib, which compares favorably to the historical ORR of 66% for ibrutinib monotherapy
    - Complete response (CR) rate of 35% for MCL patients treated with zilovertamab plus ibrutinib (9 of 26 evaluable patients), which compares favorably to the historical ORR of 20% for ibrutinib monotherapy, and with CRs remaining durable for up to 32 months
    - Median progression-free survival (PFS) of 35.9 months for MCL patients with median follow-up of 14.4 months, which compares favorably to the historical ibrutinib monotherapy median PFS of 12.8 months
    - Landmark PFS of 100% at 36 months for CLL patients who had previously received one or two prior lines of therapy, which compares favorably to historical ibrutinib monotherapy PFS of ~ 75%
    - Median PFS had not been reached for CLL patients with one or two prior lines of therapy, and median PFS was 36.1 months for patients receiving > 2 prior lines of therapy, with a median follow-up of 29.0 months
    - The combination of zilovertamab and ibrutinib continued to be well tolerated, with a safety profile consistent with or improved compared with historical data for ibrutinib monotherapy
- In November 2021, we announced joining the Karolinska Institutet's NextGenNK Competence Center to support our next generation ROR1-targeted cell therapy initiatives, and the establishment of a Cell Therapy Scientific Advisory Board, comprised of industry and academic leaders in the cell therapy field.
- In October 2021, we presented encouraging preclinical data with ONCT-534, the lead candidate in our preclinical dual-action androgen receptor inhibitor (DAARI) program, during a virtual poster presentation at the AACR-NCI-EORTC Virtual

International Conference on Molecular Targets showing anti-tumor activity in preclinical studies relevant to important tumor resistance mechanisms, including those involving expression of the androgen receptor splice variant (AR-V7).

- In November 2021, we announced an interim clinical data update from the ongoing Phase 1/2 clinical trial evaluating ONCT-216, an investigational, potentially first-in-class, targeted small-molecule inhibitor of the E26 transformation-specific (ETS) family of oncoproteins, in patients with relapsed or refractory Ewing sarcoma [CT02657005] at the Connective Tissue Oncology Society 2021 Virtual Annual Meeting. Two patients continue to demonstrate durable complete responses, including one patient with a durable CR for 24 months on treatment, and no evidence of disease off treatment after several months.

Expected Upcoming Milestones

- Zilovertamab (ROR1 antibody) program
  - Initiation of global registrational Phase 3 Study ZILO-301 in the second quarter of 2022
  - Interim clinical data update for patients with MCL and CLL treated with zilovertamab plus ibrutinib in ongoing Phase 1/2 clinical study in the second quarter of 2022
  - Have a Phase 1b investigator sponsored trial of zilovertamab plus docetaxel initiated for patients with metastatic castration-resistant prostate cancer (mCRPC) in mid-2022
- ONCT-808, lead candidate in autologous ROR1-targeted CAR-T cell therapy program
  - Investigational New Drug (IND) application submission in mid-2022
- ONCT-534, lead candidate in our DAARI program
  - IND-enabling GLP toxicology studies and GMP manufacturing initiated in the second quarter of 2022
- ONCT-216 (ETS inhibitor) program
  - Updated interim clinical data for patients with Ewing sarcoma treated in the dose intensified expansion cohort in the fourth quarter of 2022

Fourth Quarter and Full Year 2021 Financial Results

Our grant revenue was $0.6 million for the fourth quarter ended December 31, 2021. Our grant revenue is derived from a subaward under a grant from the California Institute for Regenerative Medicine (CIRM) to the University of California, San Diego and two research and development grant awards from the National Institutes of Health (NIH). For the full year 2021, grant revenue was $4.3 million.

Our total operating expenses for the fourth quarter ended December 31, 2021 were $8.6 million, including $1.7 million in non-cash stock-based compensation expense. Research and development expenses for the quarter totaled $6.0 million, and general and administrative expenses for the quarter totaled $2.6 million. Net loss for the fourth quarter was $8.1 million, or a loss of $0.16 per share, basic and diluted. For the full year 2021, total operating expenses were $35.7 million, including $5.9 million in non-cash stock-based compensation expense, and our net loss was $31.3 million, or a loss of $0.64 per share, basic and diluted.

As of December 31, 2021, we had approximately 49.4 million shares of common stock outstanding. $90.8 million in cash and cash equivalents and no debt. We believe these funds will be sufficient to fund our operations into mid-2023. Our cash guidance is subject to a number of assumptions, including those related to the severity and duration of the COVID-19 pandemic, and the pace of our research and clinical development programs, among other aspects of our business and the geopolitical environment.

About Oncternal Therapeutics

Oncternal Therapeutics is a clinical-stage biopharmaceutical company focused on the development of novel oncology therapies for the treatment of patients with cancers that have critical unmet medical need. Oncternal pursues drug development targeting promising, yet untapped biological pathways implicated in cancer generation or progression, focusing on hematological malignancies and prostate cancer. The clinical pipeline includes zilovertamab (formerly cirmtuzumab or UC-961), an investigational monoclonal antibody designed to inhibit ROR1, a type I tyrosine kinase-like orphan receptor. Zilovertamab is being evaluated in a Phase 1b/2 clinical trial in combination with ibrutinib for the treatment of patients with mantle cell lymphoma (MCL) and chronic lymphocytic leukemia (CLL), in investigator-initiated studies, including a Phase 1b clinical trial in combination with paclitaxel for the treatment of women with HER2-negative metastatic or locally advanced, unresectable breast cancer, in a Phase 2 clinical trial of zilovertamab in combination with venetoclax, a Bcl-2 inhibitor, in patients with relapsed/refractory CLL, and in a Phase 1b study of zilovertamab in combination with docetaxel in patients with metastatic castration-resistant prostate cancer (mCRPC). Oncternal is also developing ONCT-808, a chimeric antigen receptor T cell (CAR-T) therapy that targets ROR1, which is currently in preclinical development as a potential treatment for hematologic cancers and solid tumors. The clinical pipeline also includes ONCT-216 (formerly TK216), an investigational targeted small-molecule inhibitor of the ETS family of oncoproteins, that is being evaluated alone and in combination with vincristine chemotherapy in a Phase 1/2 clinical trial for patients with Ewing sarcoma. The early-stage pipeline also includes ONCT-534 (formerly GTX-534), a dual-action androgen receptor inhibitor (DAARI), that is in preclinical development as a potential treatment for castration resistant prostate cancer and other androgen-receptor dependent diseases. More information is available at https://oncternal.com/.

Forward-Looking Information
Oncternal cautions you that statements included in this press release that are not a description of historical facts are forward-looking statements. In some cases, you can identify forward-looking statements by terms such as “may,” “will,” “should,” “expect,” “plan,” “anticipate,” “could,” “intend,” “target,” “project,” “contemplates,” “believes,” “estimates,” “predicts,” “potential” or “continue” or the negatives of these terms or other similar expressions. These statements are based on Oncternal’s current beliefs and expectations. Forward-looking statements include statements regarding Oncternal’s development programs, including the anticipated timing for announcing additional preclinical and clinical data; timing of reaching any milestones, including IND submissions; timing for regulatory communications; Oncternal’s expected cash runway; and the potential that Study ZILO-301 can serve as a registrational clinical trial; and the expected initiation of clinical trials, including Study ZILO-301. Forward-looking statements are subject to risks and uncertainties inherent in Oncternal’s business, including risks associated with the clinical development and process for obtaining regulatory approval of Oncternal’s product candidates, such as potential delays in the commencement, enrollment and completion of clinical trials; we have not conducted head-to-head studies of zilovertamab in combination with ibrutinib compared to ibrutinib monotherapy and data from separate studies may not be directly comparable due to the differences in study protocols, conditions and patient populations; the risk that interim results of a clinical trial do not predict final results and that one or more of the clinical outcomes may materially change as patient enrollment continues, following more comprehensive reviews of the data, as follow-up on the outcome of any particular patient continues, and as more patient data become available; later developments with the FDA may be inconsistent with the minutes from the completed end of Phase 2 meeting, including that the proposed Study ZILO-301 that may not support registration of zilovertamab in combination with ibrutinib which is a review issue with the FDA upon submission of a BLA; and other risks described in Oncternal’s filings with the U.S. Securities and Exchange Commission. All forward-looking statements in this press release are current only as of the date hereof and, except as required by applicable law, Oncternal undertakes no obligation to revise or update any forward-looking statement, or to make any other forward-looking statements, whether as a result of new information, future events or otherwise. All forward-looking statements are qualified in their entirety by this cautionary statement. This caution is made under the safe harbor provisions of the Private Securities Litigation Reform Act of 1995.

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Oncternal Therapeutics, Inc.
Condensed Consolidated Balance Sheets Data
(in thousands)

	December 31, 2021	December 31, 2020
Cash and cash equivalents	$ 90,765	$ 116,737
Total assets	93,585	118,809
Total liabilities	5,465	5,858
Accumulated deficit	(114,130)	(82,797)
Total stockholders' equity	88,120	112,951

Oncternal Therapeutics, Inc.
Condensed Consolidated Statements of Operations Data
(in thousands, except per share data)

	Three Months Ended December 31,		Years Ended December 31,	
	2021	2020	2021	2020
	(Unaudited)			
Grant revenue	$ 556	$ 1,588	$ 4,315	$ 3,375
Operating expenses:				
Research and development	6,018	2,986	24,086	12,544
General and administrative	2,618	1,464	11,595	8,373
Total operating expenses	8,636	4,450	35,681	20,917
Loss from operations	(8,080)	(2,862)	(31,366)	(17,542)
Other income (expense):				
Other income	—	301	—	301
Interest income	7	3	33	16
Total other income (expense)	7	304	33	317
Net loss	$ (8,073)	$ (2,558)	$ (31,333)	$ (17,225)
Net loss per share, basic and diluted	$ (0.16)	$ (0.09)	$ (0.64)	$ (0.85)
Weighted-average shares outstanding, basic and diluted	49,426	29,398	49,321	20,305